

LICENSING NEWS AND VIEWS

Acquiring Medical Devices after January 1, 2000

After January 1, 2000, medical device manufacturers may continue to market devices with non-significant Y2K problems, if these (problems) are fully disclosed and present no risk to patients. This would include devices whose date related operations are not fully compliant with the strict definition of Y2K compliance used by the FDA, however, these devices may continue to be distributed and should

be safe for use according to instructions. Any new medical device acquired after January 1, 2000, should be either Y2K compliant or should have labeling that prominently discloses the existence of the Y2K problem and provides instructions for the safe use of the device. If you acquire a computer-controlled medical device that was originally marketed before January 1, 2000, you should determine the compliance status of that particular device.

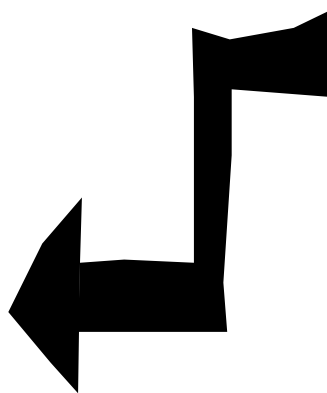
The FDA's Federal Y2K Biomedical Equipment Clearinghouse (<http://www.fda.gov/cdrh/yr2000/year2000.htm>) provides information on the Y2K status of many medical devices.



New employee? New BCI !

Recently, the Bureau has been receiving license renewals with new employees listed for BCI renewal who have a BCI clearance from employment at another licensed facility. **These applications will be rejected by the Bureau.** Every new employee must submit a BCI upon hire. Copies of a clearance issued while employed at another facility cannot be processed by the Bureau. Failure to

submit CBS/MIS Consent and Release of Liability forms within ten days of hire may result in deficiencies at the time of facility survey or renewal. If you have questions, please call Donna Riley at 801-538-9287.



Inside this issue:

Health Facility Committee Minutes	2
Breast Cancer Profile	3
Racial Equality in Kidney Transplants	3
Quality of Health Web Sites	4
Assisted Living Rules	4
A Year 2020 Snapshot	5
Accreditation for Assisted Living	5

Health Facility Committee Meeting - December 17, 1999

Sanction Actions:

1. Draper Manor Assisted Living Type II - a conditional license was issued effective 11/30/99 through 05/30/00 based on a substantiated complaint investigation and chronic noncompliance with licensing rules.
2. Woodland Park Care Center NCF - a conditional license was issued effective 09/21/99 through 02/29/00 based on substandard quality of care identified during a federal complaint investigation.
3. Bountiful Health and Rehabilitation NCF - a conditional license was issued effective 11/19/99 through 01/13/00 based on serious and immediate jeopardy to residents identified during a federal complaint investigation.

Subcommittee Reports:

1. End of Life Portability Document - the document has been completed and is being submitted for approval. This document does not replace an advanced directive, rather indicates a resident's preference in times of crises. It does not require a physician signature or a notary public signature. Following extensive discussion, a motion was made to distribute the document for review by health care agencies and associations. The motion **PASSED** unanimously.
2. Staff Ratio Committee - the subcommittee has met three times without coming to a consensus. Ms. Fitzgerald felt the issue should be looked at as part of the assisted living subcommittee rule review. The decision was made to hold subcommittee action until the HFC received a written proposal from the ombudsman.
3. Type N Sub-Committee - Ms. Siskin reported on the rule changes that have been proposed by the subcommittee. The changes are outlined on a Concept Summary form that was distributed to Committee members for review. Draft rule language will be mailed to all Type N providers and associations. The draft rule will be presented to the HFC at the March 2000 meeting. A motion was made to accept the Type N rule Concept Summary. The motion **PASSED** unanimously.
4. Assisted Living Subcommittee - the first meeting is scheduled for 01-12-00.

Other Reports:

1. CNA/Nurse Shortages - Helen Rollins of the HFC, and Debra Wynkoop-Green attended the Nursing Leadership Forum to discuss the nurse and CNA

shortage and training issues. The Forum has formed a subcommittee to discuss the issues and have invited Ms. Rollins and Ms. Wynkoop-Green to participate.

2. Report from the Utah Health Care Association (UHCA) on Governing Boards for Long Term Care facilities - Joan Gallegos reported that the issue of having a non-owner of each facility on the governing board will be discussed as UHCA updates their strategic plan in January of 2000.
3. Report on Patient/Resident Funds - the patient funds issue paper was presented to the Office of Public guardian for review. At this time the Office is unable to absorb any additional work due to lack of funding. A representative from the Office of Public Guardian will be invited to the next HFC to discuss their goals and objectives.

4. CNA/HHA Certification - Susan Lewson reported a proposal to combine the CNA and HHA into one certification. Ms. Lewson reported that hospitals and home health agencies may benefit from this change, but the UHCA and nursing care facilities will most likely oppose this change. Joan Gallegos of UHCA and Mr. Anderson of the HFC, both stated concern that this change will increase CNA movement among different health care providers. A motion was made to prepare a Concept Summary and hold public hearings on the proposed change. The motion **PASSED** by a majority vote with one member opposed. The Concept Summary will be added for discussion at the March 2000 HFC meeting.
5. Rule Changes - Concept Summary - Freestanding Ambulatory Surgical Centers - the Bureau has received nine letters from nurse anesthetists requesting a rule change. A motion was made to form a subcommittee to review the CRNA scope of practice in the ASC rules. The motion **PASSED** unanimously. Dr. Clayton will chair the subcommittee with Craig Christopherson as Bureau support.

Other Issues:

1. Ms. Wynkoop-Green proposed that the next Health Facility Committee meeting scheduled for 01-28-00 be canceled to allow subcommittees to develop written documents. All HFC members agreed.
2. A Health Systems Improvement announcement for all health facilities concerning Y2K was distributed. Ms. Gallegos stated that facilities need to make sure equipment purchased after 01-01-00 complies with Y2K.

The next Health Facility Committee Meeting is scheduled for March 24, 2000, in Room 114 at the Cannon Health Building.

Breast Cancer Profile

- Breast cancer is the leading cause of death among women 40 to 55 years old in the United States.
- Inherited breast cancer accounts for only 5% to 10% of all breast cancers.
- Approximately 75% of the breast cancers diagnosed each year occur in women over the age of fifty.
- Women who have had cancer in one breast run an increased risk of developing cancer in the other breast.

(Source: National Cancer Institute)

Regulatory Web Sites

- Bureau of Licensing -
<http://www.health.state.ut.us/his/hfl>
- Utah Administrative Code -
<http://www.rules.state.ut.us>
- Utah Code Annotated -
<http://www.le.state.ut.us>
- ADA Document Center -
<http://janweb.icdi.wvu.edu/kinder/index.htm>
- ADAAG Guidelines -
<http://www.access-board.gov/bfda/adaag.htm>

HCFA Announces New Steps for Racial Equality in Kidney Transplantation

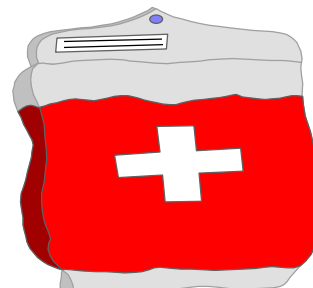
The Health Care Financing Administration is taking steps to ensure that all patients with renal failure, regardless of race, are being evaluated for kidney transplantation. The effort will include communication, enforcement and technical assistance to dialysis centers. "Medicare rules require that all patients with kidney failure be evaluated and informed about transplantation," said HCFA Administrator Nancy-Ann DeParle. The Medicare program provides insurance coverage for virtually all Americans with permanent kidney failure, paying for dialysis and transplantation through the End Stage Renal Disease (ESRD) program. Medicare will take a three-pronged approach to addressing transplant assessment disparities:

1. The program will remind all certified ESRD facilities of the requirement that all ESRD patients are assessed for and fully informed about transplantation as part of the patient's long-term care plan.

2. HCFA will work with state survey agencies in evaluating findings and paying particular attention to dialysis facility compliance with regulations.

3. Medicare will work with the ESRD Network Organizations to identify ways that the Networks can work with the patients, the renal community, and the dialysis facilities in their area to increase transplantation assessment rates.

"All three approaches will enforce and reinforce Medicare's commitment to its ESRD beneficiaries by assuring that they will receive the quality of care that they depend on, including the opportunity to be fully informed about and assessed for transplantation," DeParle stated.



FLU FACTS:

Annual influenza (flu) shots are recommended for people at high risk of a serious complication if they get the flu. Groups at risk include:

Persons Over 65 years of age.

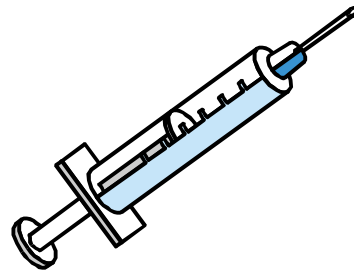
Residents of nursing homes and chronic-care facilities.

Adults and children who have chronic illnesses, such as pulmonary (including children with asthma), cardiovascular, diabetes, renal dysfunction, hemoglobinopathies, or immunosuppression (including that caused by medications).

Children and teenagers (6 months – 18 years) who are receiving long-term aspirin therapy and, therefore, might be at risk for developing Reye syndrome after the flu.

Women who will be in the second or third trimester of pregnancy during the flu season. Vaccination is also recommended for health care workers and others in close contact with high risk persons, and for people who would perform essential services during an outbreak.

(Source: Center for Health Data, Utah Department of Health)



STATE FIRE MARSHAL **RULES, R710-3 & 4 ARE APPLICABLE TO ASSISTED LIVING FACILITIES**



The Bureau would like to remind all assisted living facilities that the state fire marshal rules are applicable. Section 3 of R710 requires the following:

- Staff training in usage of all emergency equipment including portable fire extinguishers,
- All I occupancies with restrained occupants shall be staffed at all times (Alzheimer's Units),
- Dead bolts may only be used if simultaneous retraction is provided.; i.e. the dead bolt retracts when the door knob is turned. This also eliminates the use of double action locking devices,

- Limitations of where residents in limited capacity facilities can be housed. (main level only unless an approved exit is provided from that level),
- Limited capacity facilities must have escape windows and smoke detectors in sleeping rooms and hallways.

Section 4 of R710 references NFPA 72 which requires that smoke detectors connected to an alarm system must be sensitivity tested as well as functionally tested. Larger facilities may have alarm panels that have an automatic testing system that will alarm if sensitivity is a problem. Otherwise, systems detectors must be sensitivity tested within one year of installation and every alternate year thereafter. There is also a provision that if the detector is within its listed range after the second test, then subsequent testing can be extended to no more than five years.

If you have any questions, please call Larry Naylor at 435-674-3823 or Craig Christopherson at 801-538-6327.

A Year 2020 Snapshot???

What will healthcare in the year 2020 look like?
Richard Smith, MS, a futurist with
Washington D.C. - based Coates and Jarratt,
provides some crystal ball forecasts:

- 80% of ambulatory care will be resolved by telemedicine.
- More than 75% of health treatments will be delivered by non-physicians.



- Hospital patient day averages will plummet; the number of beds will be reduced nationally to 300,000.

- Most routine business transactions will take place between a human and a virtual personality.

- Tele-diagnosis and call centers will be cheaper to society than ambulatory care centers and hospitals.

(Article adapted from: Managed Healthcare News, November, 1999)

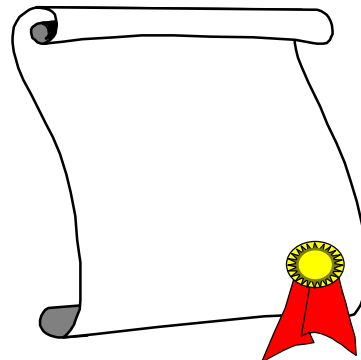
Accreditation for Assisted Living

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and Rehabilitation Accreditation Commission (CARF) are developing separate accreditation standards for assisted living facilities. Both organizations would focus on encouraging assisted living companies to provide the best care possible to consumers.

JCAHO will focus on performance based standards, science-based outcomes measures and quality improvement analytical techniques. The standards are available on JCAHO's website: www.jcaho.org. JCAHO hopes to have collected pilot test results incorporated into the standards, and have the standards available July 2000. They hope to begin conducting surveys in January of 2001.

CARF announced in September, plans to develop its national voluntary accreditation process for assisted living providers to be in place by July 1, 2000. CARF says its accreditation system focuses on peer review, networking, and sharing ideas. They strive to develop standards that emphasize outcomes and maintain the wide variety of choices consumers have today. CARF standards are available for review at: www.carf.org.

Site visits that lead to accreditation in assisted living are expected to begin July 1, 2000.



Utah Department of Health
Bureau of Licensing
PO Box 142003
Salt Lake City, Utah 84114-2003

*BULK RATE
U.S. POSTAGE
PAID
SALT LAKE CITY, UT
PERMIT NO. 4621*

Debra Wynkoop, Bureau Director	dwynkoop@doh.state.ut.us	801-538-6152
Wendee Pippy, Support Services Coordinator.....	wpippy@doh.state.ut.us	801-538-6322
Marsha Bentley, Health Program Representative ...	mbentley@doh.state.ut.us	801-538-6207
Joel Hoffman, Manager Central Region.....	jhoffman@doh.state.ut.us	801-538-6165
Craig Christopherson, Team Leader	cchristo@doh.state.ut.us	801-538-6327
Paul Lund, Health Licensing Specialist ...	plund@doh.state.ut.us	801-538-6630
Betsy Baker, Health Licensing Specialist ...	ebaker@doh.state.ut.us	801-538-6328
Sharon Mccombs, Complaint Coordinator	smccombs@doh.state.ut.us	801-538-6778
Bill Bonn, Architect	wbonn@doh.state.ut.us	801-538-6781
Joan Isom, Executive Secretary	jisom@doh.state.ut.us	801-538-9084
David Eagar, Manager Provo Region.....	deagar@prc.state.ut.us	801-374-7803
David Shorten, Team Leader	dshorten@prc.state.ut.us	801-371-1065
Joyce Beckstrom, Health Licensing Specialist	jbeckstrom@doh.state.ut.us	801-371-1158
Nedra Slock, Secretary	nslock@prc.state.ut.us	801-374-7688
Larry Naylor, Manager Dixie Region.....	lnaylor@doh.state.ut.us	435-674-3823

Web Site: <http://www.health.state.ut.us/hsi/hfl>